Evaluation of the PATH-SAFE programme

Evaluation framework report

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Abbreviations

A	activities
AMR	antimicrobial resistance
APHA	Animal and Plant Health Agency
CA	contribution analysis
CEFAS	Centre for Environment, Fisheries and Aquaculture Science
CMO	context, mechanisms and outcomes
DAG	Data Advisory Group
DEFRA	Department for Environment and Rural Affairs
DHSC	Department of Health and Social Care
EA	Environment Agency
EQs	evaluation questions
EU	European Union
FBP	Foodborne pathogen
FSA	Food Standards Agency
FSS	Food Standards Scotland
HMT	His Majesty's Treasury
LAMP	Loop-mediated isothermal amplification
NBN	National Biosurveillance Network
O	Outputs
OECD	Organisation for Economic Cooperation and Development
PATH-SAFE	Pathogen Surveillance in Agriculture, Food and Environment
PHA	Public Health Agency
SAG	Scientific Advisory Group
ToC	Theory of Change
UKHSA	UK Health Security Agency

VMD	Veterinary Medicines Directorate
WGS	whole genome sequencing
WHO	World Health Organisation
WS	workstream

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1.   Introduction

This report sets out the evaluation framework that will be used to guide the evaluation of the Pathogen Surveillance in Agriculture, Food and Environment (PATH-SAFE) programme. The report is intended for HM Treasury as the programme sponsor and delivery partners of the programme, primarily Food Standards Agency (FSA), Food Standards Scotland (FSS), Department for Environment and Rural Affairs (DEFRA), UK Health Security Agency (UKHSA), Department for Health and Social Care (DHSC), and the Environment Agency (EA). The findings of the evaluation will help the delivery partners manage PATH-SAFE adaptively and assess the impact created through the programme on foodborne pathogen and antimicrobial resistance surveillance. The report is structured as follows:

- The remainder of this introduction describes the context for the PATH-SAFE programme, the goals and structure of the programme, the aims of the evaluation and its limitations, and our approach to developing this evaluation framework report.

- Chapter 2 presents the analytical framing for the evaluation comprising the PATH-SAFE theory of change (ToC).

- Chapter 3 describes our overarching evaluation approach through which we will collect evidence to assess the PATH-SAFE programme. The evaluation approach will comprise three types of evaluation: a process evaluation; an outcome evaluation; and an impact feasibility assessment.

- Chapter 4 presents the process and outcome evaluation frameworks through which the evaluation of the PATH-SAFE programme will be operationalised. Presented in tabular form, each framework comprises key evaluation questions (EQs), derived from the PATH-SAFE ToC, which our evaluation will seek to answer, alongside indicators and proposed data sources. The chapter builds on the frameworks and provides further detail on the methodology that will be undertaken to conduct the evaluation.

- Chapter 5 shows the evaluation timelines and key deliverables.

- Chapter 6 outlines the risks to the evaluation and our mitigations in place.

- The Annexes to the report contain additional information on the four workstreams (WSs) and sub streams of the PATH-SAFE programmes (Annex A), which is useful context for the evaluation frameworks, and more detailed information on the activities that led to the development of the evaluation framework report (Annex B) and the process and outcomes evaluation frameworks (Annex C).

1.1.   Background

Foodborne diseases pose a major public health risk to the UK population, and creates a significant burden on our health services and economy. The majority of human disease is caused by a handful of pathogens that, in most cases, enter the food chain from farmed animals or the environment. In addition, these foodborne pathogens can also develop antimicrobial resistance (AMR) due to the overuse of antimicrobials in food production

systems. Since they are transmissible to humans via the food chain, causing illness and disease, antimicrobial-resistant foodborne pathogens are a global health issue affecting countries of all economic levels. The combined threat of foodborne and AMR pathogens creates a crucial risk for the food chain as well as the environment and need to be investigated and monitored holistically.

For AMR specifically, as its disease and economic burden rises globally, there is significant demand for new and emerging diagnostic and identification technologies to reduce its spread together with a coordinated and collaborative regulatory approach. According to the World Health Organisation (WHO), antimicrobial resistant infections are estimated to cause around 700,000 deaths each year, a figure which is expected to rise to 10 million deaths by 2050. They also pose a significant economic threat that could cost a cumulative 100 trillion dollars of economic output within the same timeframe. In January 2019, the UK government published a 5-year action plan to tackle AMR, developed as a cross-governmental effort in collaboration with a range of stakeholders across academia, industry, and professional bodies. The action plan included measures to improve the development and access to diagnostics, and adopted a 'One Health' approach, setting out commitments that cut across human and animal health, as well as food production and the environment. A coordinated, multi-sectoral 'One Health' response to surveillance of foodborne pathogens and AMR is possible with the research and development of new and safe antimicrobials, diagnostics, vaccines, waste management tools, as well as the availability of affordable and quality versions for both animals and humans. The ambitions of the UK government-funded PATH-SAFE programme integrate cohesively into this approach.

1.2. The PATH-SAFE Programme

PATH-SAFE is a pilot programme that aims to develop comprehensive surveillance of foodborne pathogens (FBPs) and AMR in all four nations of the UK. It proposes to create a national genomic surveillance infrastructure, through improved and novel uses of data and technology creating a blueprint for national surveillance. Through a range of parallel proof of concept pilot workstreams, it will demonstrate how this infrastructure will support a national roadmap for One Health surveillance across the UK.

The PATH-SAFE programme is funded by HM Treasury through the Shared Outcomes Fund. This Fund was established to pilot projects to test innovative ways of working across the public sector. It has had two rounds of funding, in 2019 and 2020, with a £200 million allocation in each round. PATH-SAFE was funded in round 2 with a funding allocation of £19.2 million which will last until 2024. It is a cross-governmental collaboration across the FSA, FSS, DHSC, DEFRA, UKHSA, and the EA.

The PATH-SAFE programme consists of four workstreams (WSs,), which are summarised below, and are being delivered through multiple partners from the government departments and their agencies, centres and directorates mentioned above as well as devolved

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administrations in Wales and Northern Ireland and a variety of academic institutes. Further details on the WSs and their sub streams can be found in the Annex.

WS1: Establish a curated, national foodborne disease genomic data platform

This WS's key ambition is to work with academic colleagues and major 'big data' stakeholders to create a 'user-friendly' platform for the rapid interrogation and of genomic data. They will build easy to use reporting capabilities to create powerful, but easily understood, interfaces that can be used by decision makers (for example, epidemiologists or other public health professionals). A key element of the data platform development will be allowing the integration of sample data with other existing data sources to create new knowledge.

A distinct project of the WS is WS1b which is focussed on understanding source attribution, infection threat and level of AMR of E. coli. in Scotland using whole genome sequencing, with samples isolated from a range of reservoirs across Scotland.

WS1 is led by FSA and delivered by a consortium of government and academic partners (Project 1a) and FSS (Project 1b) and is due to finish in March 2024.

WS2: Develop a pilot infrastructure for regular, multi-location sampling

The WS will develop a pilot infrastructure to provide high granularity whole genome sequencing (WGS) data from regular, multi-location sampling of wastewater and food products to capture AMR and FBP data. This is being done across multiple projects and multiple settings (for example, milk laboratory, sheep abattoirs etc.).

WS2 is led by Defra and delivered by the Centre for Environment, Fisheries and Aquaculture Science (CEFAS) (Project 2a); Animal and Plant Health Authority (APHA)/Veterinary Medicines Directorate (VMD) (Project 2b); Public Health Agency Northern Ireland (PHA NI) (Project 2c) and FSA (Project 2d) and is due to finish in March 2024.

WS3: Understand the feasibility of using portable diagnostics as inspection tools

The WS will investigate the technology readiness levels of existing and new portable diagnostics. The results of these studies will inform options for in-field testing and/or development. The co-design of applications with end-users (for example, policy teams/inspectorates, operational staff) will be critical to ensure real-world applicability. The WS will also undertake a pilot study investigating the feasibility of using wastewater approaches developed in response to the Covid-19 pandemic with complimentary diagnostic technology (for example, Loop-mediated isothermal amplification or LAMP) to understand Norovirus outbreaks in a contained setting. WS3 is led by FSA and delivery by Fera Science Ltd. (Project 3a) and UKHSA (Project 3b) and is due to finish in March 2024.

WS4: Develop a pilot environmental AMR surveillance system

The overall aim in WS4 is to create an evidence-based understanding of the nature and extent of AMR in the environment and the drivers that influence this. This pilot will deliver an agreed and tested methodology for environmental AMR surveillance, as well as an environmental information technology (IT) platform that aims to enable a scaled-up surveillance programme to be undertaken. This IT platform will be designed and developed so that it will have the

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capability to integrate AMR surveillance data collected from animals so that the ambition of having a UK 'One Health' surveillance system for AMR can be realised. WS4 is led by DEFRA (with EA and VMD) and UKHSA and is due to finish in June 2023.

Figure 1**. PATHSAFE WSs**
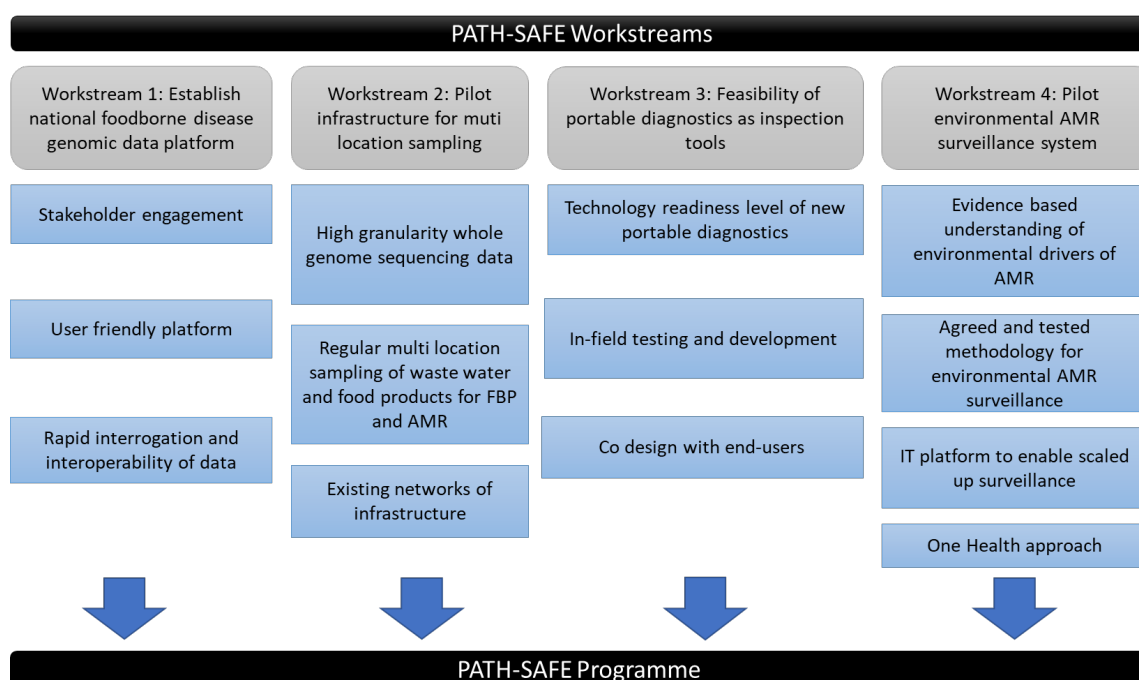
1.3.   Evaluation of PATH-SAFE

In November 2022, FSA commissioned RAND Europe to undertake the evaluation of the PATH-SAFE programme. There are three main objectives of the evaluation:

- Design and framing: to design a programme ToC for the programme, articulating the change that is intended to be achieved by PATH-SAFE. This includes outlining assumptions, external factors and managing risks associated with the programme.

- Formative process evaluation: to utilise bespoke evaluation methods for assessing the processes underpinning the programme and delivering the outputs of the four WSs to identify areas for learning and improvement.

- Understanding impact: to identify and prioritise outcome indicators and data sources to validate the outcomes of the ToC and develop an assessment of PATH-SAFE's contribution.

The main evaluation questions to be addressed in the process and outcome evaluations are listed below and can also be found in Table 1 and Table 2:

- How appropriately resourced has PATH-SAFE been throughout the stages of inception, design and implementation?

- How effective and appropriate is the governance in place to support delivery of PATH-SAFE?

- How is cross-government interaction being enabled/conducted?

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- How is PATH-SAFE linked to existing/developing surveillance programmes?

- To what extent have relevant end users been engaged and how has have their needs been incorporated into the design of the database?

- How has data interconnectivity and interoperability been considered in designing the platform?

- What existing and novel analysis technologies are being utilised?

- What is the extent of data collection and curation?

- How (if at all) are new capabilities being generated to improve surveillance?

- How is data being accessed/ shared across relevant stakeholders and departments?

- To what extent is the technology readiness level (TRL) assessment approach valuable for identification of relevant technology?

- How is LAMP assessment feeding into TRL mechanisms for FBP diagnostics?

- What is being learnt and incorporated from existing AMR surveillance systems and tools?

- How is connectivity between the WS4 AMR environment platform and WS1a being considered?

- How is evidence being aggregated across the multiple departments involved in WS4 delivery?

- How has PATH-SAFE (if at all) enabled a community of practice and decision makers to come together to inform and act on surveillance of FBPs and AMR?

- How and to what extent has PATH-SAFE evidence (if at all) contributed to national policies and frameworks for improved public health?

- Has data access and use for FBP and AMR been enabled and improved across government departments?

- To what extent has the platform supported use of relevant metadata and historic isolates for comparative assessments and risk profiles of FBP?

- How has the collective source detection efforts and use of novel technology translated to (if at all) improved surveillance of FBP and AMR?

- To what extent have the pilot efforts been able to exemplify practice and enhance national surveillance capability?

- What kind of strategies and operations have been enhanced, enabled and influenced enabled (if at all) through the surveillance activities?

- Have the tools identified been useful for end users? Can they be utilised?

- To what extent have gaps been identified to further development of onsite rapid FBP detection?

The PATH-SAFE evaluation will look to understand existing surveillance mechanisms that precede the programme, which will be useful context for assessing the additionality of PATH-SAFE. The evaluation project will run from November 2022 to June 2024

1.4.   Evaluation framework report

This document presents the evaluation framework report for PATH-SAFE. The purpose of the report is to detail our evaluation approach, including evaluation questions as well as data collection and analysis methods to guide the process and outcome evaluations of PATH-SAFE. We outline the key activities undertaken by the evaluation team to inform the development of this report in Annex B.

1.5.   Developing the Process and Outcomes evaluation frameworks

The evaluation frameworks were developed systematically by reviewing and refining the EQs initially provided by FSA (developed with the programme partners) and developing new additional ones. The EQs were mapped to all key outputs and outcomes of the ToC to ensure coherence. Against each EQ, process and outcome indicators were developed which were then mapped against relevant data sources and the data collection methodology. We list the key activities undertaken by the evaluation team to inform the development of these frameworks in Annex C.

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2.   Analytical framing

This chapter sets out the analytical framing for the evaluation of the PATH-SAFE programme. We have chosen a theory-based approach for this evaluation. Whilst experimental evaluation approaches usually measure the effect of an intervention in comparison to a counterfactual group, hence assessing the causal relationship between an intervention and its effects, they do not uncover *why* the intervention worked or not and *how*, if it did. A theory-based evaluation addresses these questions and considers the complexity within which an intervention is being delivered. The combination of complexity of the external environment, large and disparate areas of focus for the WSs, and lack of a counterfactual makes a theory-based approach the most useful and feasible for the PATH-SAFE evaluation. Given the use of a theory-based approach, the evaluation of PATH-SAFE is underpinned by a ToC described below, which is the foundational structure used to develop the evaluation framework presented in Chapter 4.

2.1.   PATH-SAFE ToC

A ToC, read from left to right, is a programme theory that hypothesises the intended change an intervention is likely to bring about. It assumes a causal relationship between the intervention activities and its outputs and outcomes. An integral part of conducting a [robust evaluation](), a ToC helps articulate how various programme inputs and activities are expected to work, as well as identify the strength of the evidence that underpins them. However, the further one moves to the right-hand side of the ToC and the longer term the outcomes and impacts become, the effect or the contribution of the intervention becomes diluted and direct causality is less attributable. To account for this dynamic programme environment and complexity, an iterative and participatory approach to refining the ToC was followed, involving key stakeholders and triangulation with desk research. This approach is also in alignment with the [Magenta book guidelines]() on handling complexity in policy evaluation while developing the logic model for a ToC.

A ToC serves two broad purposes:

- It clarifies for stakeholders the role they can play in accomplishing the goals of the intervention through articulating a shared understanding of the aims of the intervention in question and how these will be achieved.

- It also functions as a tool, a base framework upon which to map evaluation questions, indicators, and data sources by displaying the logic through which the performance of the intervention can be assessed (see Chapter 4. Evaluation framework).

FSA, in conjunction with programme partners, developed a ToC for the PATH-SAFE programme that was shared with RAND Europe. This ToC adopted the standard logic model approach of modularly stating inputs, activities, outputs, outcomes and impacts of the programme. After documentary review, consultation with subject-matter experts, and a validation workshop with the central team, we revised the original ToC by providing more specificity in the outputs and outcomes of the programme and a clear linkage between these and the four WSs.

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As an example, the original output listed for WS1, "Pilot FBP/AMR genomic data system using exemplar species", was divided into two separate outputs that differentiated between the delivery of the database itself and its ability to integrate with other data systems (see 'Outputs' column in Figure 2.) Similarly, the original list of five outcomes were expanded and further nuanced to take into account the anticipated changes realised through the four WSs as well as changes achieved by the programme holistically building on the individual outcomes of the WSs. For instance, WS2 has been expanded to contribute to distinct outcomes. This includes the original outcome focused on understanding source attribution of FBP and AMR, with an added focus on infection threat as well as an explicit mention of international entry points in the newer version.

Additional outcomes focused on bringing together key stakeholders and decision makers to engage with key evidence, and contribution to 'One Health' goals and ambitions for public health have been added to signify the holistic change anticipated at the programme-level. The revised ToC is presented in Figure 2, and will be edited following the impact feasibility assessment (see Section 3.3). The activities and outputs are intended to be carried out and delivered by March 2024 when the current phase of funding completes. The outcomes and impacts are anticipated to be realised over the medium (2-5 years) to long-term (5-10 years).

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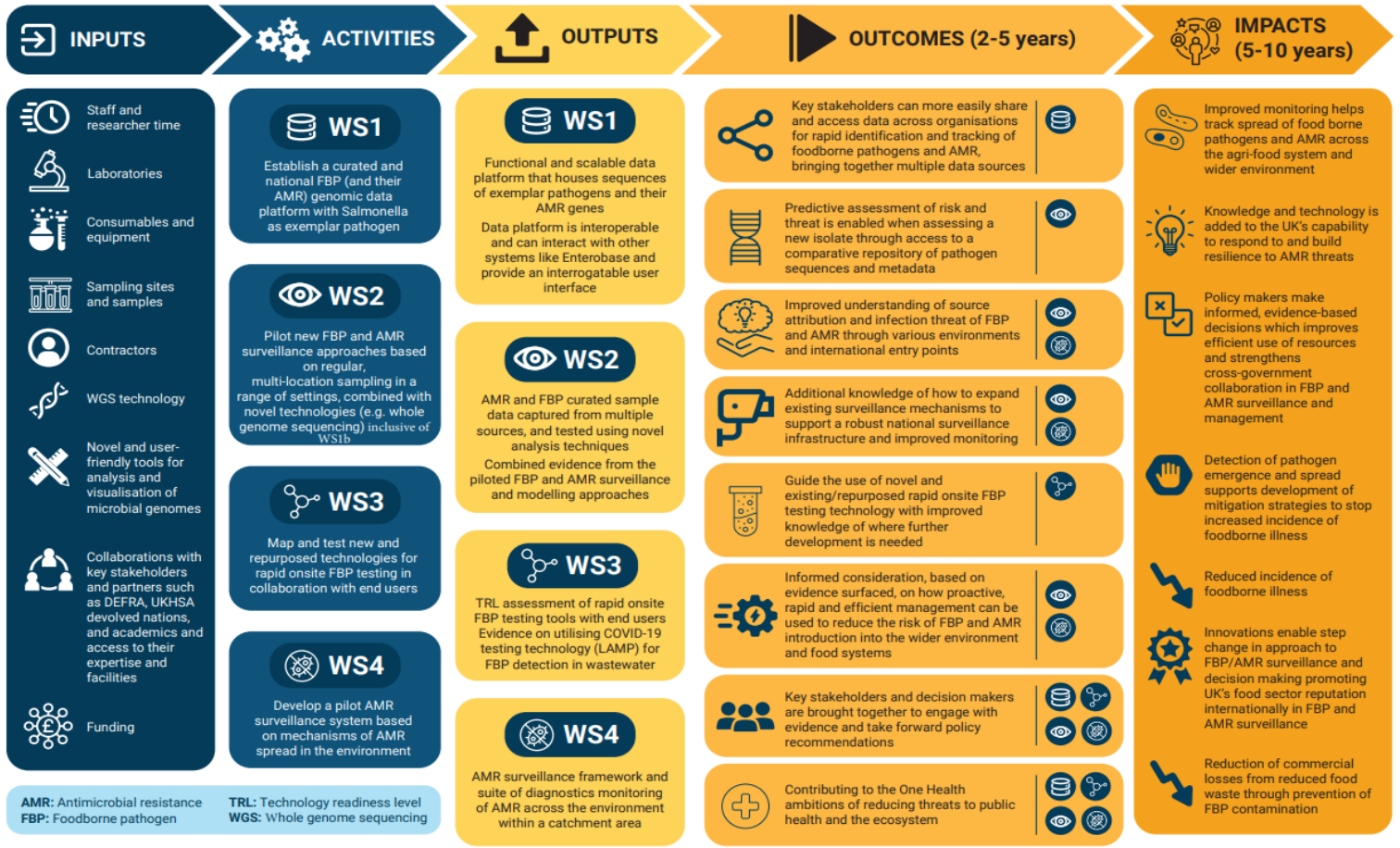
Figure 2 PATH-SAFE programme ToC

2.2.   Factors influencing the ToC

This section outlines the main assumptions that need to be fulfilled for the ToC to be realised and the external factors to be aware of in the evaluation. These are key factors that could impact the programme's delivery, so the evaluation needs to refer to these in its methodological approach. The original assumptions underpinning the ToC, provided by the central programme management team, were modified based on the documentary review and desk research conducted, when revising the ToC. Furthermore, a list of external factors was developed, supported by desk research, that could affect the delivery of PATH-SAFE and hence impact the ToC and the ensuing evaluation. The list of assumptions and external factors presented is not exhaustive and, where appropriate, will be revisited at the conclusion of the evaluation.

2.2.1.   ToC assumptions

The ToC is underpinned by a range of assumptions about the expected behaviour of key entities across the PATH-SAFE programme, which in turn affect the realisation of the intended outputs and outcomes of the intervention. These assumptions cover the actions of end users, stakeholders, and the programme itself. We have identified the following as relevant for the PATH-SAFE programme:

- End users know about and engage with programme outputs facilitated through a strong engagement strategy.

- Key collaborations, with stakeholders needed for programme delivery, are established and maintained at the programme and project level.

- Datasets, surveillance systems, and innovations are fit for purpose and functional to track AMR and FBP.

- Further funding covers running costs of legacy products and financial input continues until projects draw to a close with a plan for infrastructure maintenance.

- There is use of systems and frameworks produced from the programme across the agrifood landscape in the UK.

- Programme activities are commissioned and awarded on time and as intended.

- Programme funds activities that align with the aims of PATH-SAFE.

2.2.2.   ToC external factors

The implementation of the PATH-SAFE programme is taking place in an environment that includes exogenous shocks such as the UK's exit from the European Union (EU) and Covid-19, and other relevant initiatives in the broader ecosystem of pathogen surveillance and detection. Exogenous shocks can result in significant changes to the economic and societal landscape within which PATH-SAFE operates. EU exit, for example, could impact which pathogens are selected for surveillance due to divergent policies on AMR and crop technologies between the UK and the EU. Covid-19 and the ongoing war in Ukraine, other shock variables, have already compressed resource availability and the ability to deliver

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projects as intended. Beyond shocks, we also include relevant initiatives that could impact PATH-SAFE delivery or affect its intended outcomes and impacts by either accelerating or hindering them (for example, the UK national action plan for AMR). These activities can help us assess where the contributions of PATH-SAFE are unique and where they form part of a larger effort across the UK and international agri-tech sector. They will also show us whether PATH-SAFE is compatible with other interventions that predate it and are in development (see Section 3.2).

The external factors identified so far are as follows:

Shocks

- External events (for example, Covid-19, war in Ukraine) may impact resource availability across the program, impacting ability to deliver as intended.
- EU exit's effect on UK and EU divergence on AMR policies and crop technologies could impact how, when, and on what pathogens the surveillance is conducted and also contribute to PATH-SAFE impacts.

Relevant initiatives that may impact PATH-SAFE outputs and outcomes

- UKHSA investment into another surveillance platform, developing data linkage pipelines with NHS hospital episode statistics, could fortify or detract from PATH-SAFE impacts.
- UK National Action Plan for AMR entailing reduction in use of antibiotics in livestock will impact AMR surveillance datasets and mapping.
- Investment of $1 billion by industry to set up the AMR Action Fund to bring 4 new antibiotics to market by 2030 will potentially have an impact on AMR reduction but this is outside the timelines of PATH-SAFE. The lead candidates are BV100, BV 200, BV300, and BVL-GSK098.
- Work carried out by Centre for Genomic Pathogen surveillance, enabling genomic data for surveillance of AMR tracking in the UK and globally could be complementary to or overlapping with PATH-SAFE.
- WHO's Global Genomic Surveillance Strategy 2022-2032 for pathogens with pandemic and epidemic potential, which aims to facilitate connectivity between different disease control programs and surveillance networks, has the potential to improve the PATH-SAFE outputs.
- Centre for Pandemic Preparedness developing a global early warning system to detect new infectious disease threats by bolstering surveillance and sequencing capacity could provide an opportunity for learning or to contribute to a global agenda thus realising PATH-SAFE outcomes and impacts.
- EU Farm to Fork Strategy (2020): Its objective is the reduction by 50% of the overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030. It will impact AMR surveillance and mapping and will need to have coherence against PATH-SAFE systems.

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- Climate change sector policy impact on use of genetically engineered/genetically modified editing in the agrifood sector could impact how, when, and on what pathogens the surveillance is conducted and also contribute to PATH-SAFE impacts.
- A new National Biosurveillance Network (NBN) is about to enter a discovery phase and will form part of Pillar 3 "Detect" of the new Biological Security Strategy. The aim of the discovery phase is to understand biosurveillance capabilities and then develop a biosurveillance 'pilot' business case, covering all biological threats. The NBN could offer legacy opportunities for PATH-SAFE if FBP and associated AMR are deemed to be within scope.

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3. Evaluation approach

This chapter details our overarching evaluation approach and frameworks that will be utilised for conducting the theory-based evaluation. We propose to conduct three types of assessments: a process evaluation; an outcome evaluation based on contribution analysis methodology; and an impact feasibility assessment using an adapted context mechanisms and outcomes framework. The sections below provide more information on the aims of each assessment.

Figure 3. Evaluation approach

3.1. Process evaluation

The process evaluation establishes how the programme is working, whether it is progressing as intended, and identifies any lessons learned that can be applied to programmes that are still ongoing as well as their future iterations. It will use the Organisation for Economic Cooperation and Development (OECD) evaluation criteria of relevance and coherence, assessing if the intervention is doing what it should (for example, incorporating needs of stakeholders and considering the context), and whether it is compatible with other interventions (carried out by programme partners or other actors) that predate it or are in development within the same field.

Our process evaluation is based on the ToC, focussing on the inputs, activities, and the resulting outputs of the PATH-SAFE programme and its WSs. The process evaluation will consider the mechanisms and structures in place leading to the delivery of outputs, which are primarily governance arrangements, cross-government collaboration, delivery barriers and enablers, links with existing surveillance and monitoring approaches, and end user

engagement. Given the programme is a pilot and looking to build on existing capabilities as well as generate new ones, the process indicators will be focussed on considering 'the extent' to which activities have created step change and resulted in the anticipated outputs rather than looking to quantify processes.

3.2.   Outcome evaluation

The outcome evaluation will be focussed on whether the programme and its WSs have realised the changes expected at a given point in time and determine how the changes may or may not have occurred. The goal of the outcome evaluation is not to attribute outcomes exclusively to PATH-SAFE but rather to provide evidence-based explanations of whether and how the programme contributed to the outcomes of interest alongside other external factors through undertaking contribution analysis (CA) (see Section 3.4.1 Contribution analysis). Given the start of the programme in early 2022, most outcomes will likely not have emerged at the time when the evaluation is being conducted and concluded. Therefore, the contribution claims assessment will look to focus on iterative trends and leading indicators of progress. The outcome evaluation will use the lens of the OECD evaluation criteria of effectiveness in assessing if PATH-SAFE is on the path towards accomplishing its objectives.

3.3.   Impact feasibility assessment

The impact feasibility assessment is an exercise to determine how to best evaluate the longer-term impact of PATH-SAFE. The assessment of outcomes based on the CA methodology witll provide us with a useful baseline of impact and whether the contribution claims beign tested are realistic or feasible. It will clarify which impacts remain relevant for the programme and what methodologies and indicators may be useful to consider. We will adapt and use the context, mechanisms and outcomes (CMO) framework, usually used in a realist evaluation approach (see section 3.4.2 Context, Mechanism, Outcomes Framework), to develop projections of impact. The purpose of utilising a CMO-style framework is not to actually conduct an impact evaluation using the CMO which would duplicate the work of the CA analysis, but rather to use the CMO in a novel way to create hypothesis of what the future outcomes/impacts might be, what the potential mechanisms of action and the context for it might be. This will be entirely based on the knowledge amassed from the process and the outcome evaluation, which will culminate in the CA. The outputs of the CA will inform the CMO style projections/hypotheses. The study team will reflect on the PATH-SAFE context (for example, the external environment) to assess its potential effect on outcomes yet to be realised, and also consider the mechanisms in place in the PATH-SAFE programme (uncovered during the process and outcome evaluation) that are contributing and could continue to contribute to realising the anticipated outcomes and impacts. We will **not be undertaking a CMO evaluation** but rather utilising the framework for considering appropriateness of PATH-SAFE future outcomes and impacts and their potential realisation pathways which can inform a future measurement approach.

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3.4. Methodological frameworks

The theory-based approach being utilised is underpinned by the programme ToC discussed in Section 2.1. Further to that, the outcome evaluation will be analysed through the framework of contribution analysis to assess PATH-SAFE's contribution to outcomes and impacts, while the impact feasibility assessment will be undertaken using an adapted CMO framework.

3.4.1. Contribution analysis

To help attribute causality in a programme of this size and complexity, this theory-based evaluation will use the CA methodology on the data collected. CA is a method for assessing causal claims that examines the contribution of an intervention to observed results. It provides a framework for capturing progress towards aims at a relatively early stage through testing working hypotheses and establishing a case to explain the contribution made by PATH-SAFE and its projects over alternative hypotheses. Determining contributions requires qualitative methodologies (for example, deciding whether the relevant evidence has been identified, or if it is sufficient to discard alternative hypotheses), but is informed by both quantitative and qualitative evidence from all the methods undertaken throughout the evaluation. We will place greater weight on findings stemming from multiple data sources to assess the added value and true contribution of PATH-SAFE to the outcomes anticipated and realised. See Chapter 4 for further details on how this will be done.

3.4.2. Context, Mechanism, Outcomes Framework

The impact feasibility assessment will be conducted through utilising the CMO framework. The CMO framework will be used to create a projection of how the outcomes and impacts of PATH-SAFE may arise, as anticipated, based on the ToC. This projection will rely on abductive reasoning and the evidence gathered during the evaluation on identifying contextual factors and trends, as well as identified mechanisms of actions within PATH-SAFE. This assessment will allow us to iterate on the ToC and develop a realistic measurement approach for a longer-term and/or follow-up evaluation of PATH-SAFE. As mentioned above, the data gathered during the evaluation culminating in a CA will inform the basis of the CMO projection exercise. Although we are not undertaking a CMO based realist evaluation, the use of this framework provides a useful and structured template for impact feasibility assessment.

An illustrative example of a projection for PATH-SAFE utilising CMO is depicted in Figure 4 below. When assessing one of the anticipated impacts of PATH-SAFE, preventing the increase in foodborne illness, the evaluation of PATH-SAFE could help identify the mechanism through which this could occur. In this instance, work of WS3 could result in identification and development of onsite diagnostics for FBP and AMR which, if adopted, could help decrease the incidence of foodborne illness. This change might be possible if the technology in question is scalable and can be commercialised. This is an entirely hypothetical projection and will need to draw on the PATH-SAFE evaluation for validity. The next step after creating the projections would be to develop recommendations to modify outcomes and impacts in the original ToC (if required) and to propose methods for conducting future-focussed evaluations.

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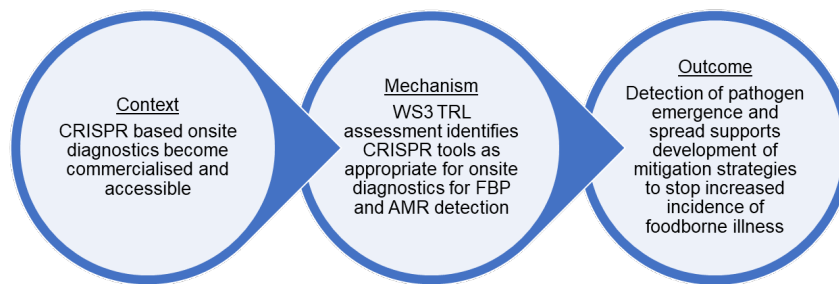
Figure 4. Illustrative example of CMO analysis

3.5.   Limitations of the evaluation approach

The approach and methodologies outlined in the chapters above will provide a wide-ranging set of data and evidence around the ambitions of the PATH-SAFE programme, and whether these ambitions have been achieved. However, our approach to the evaluation is also subject to a number of important limitations.

Firstly, whilst our approach aims to be comprehensive and cover different impacts of the PATH-SAFE programme, the lack of counterfactuals to compare the programme against poses a significant limitation. The programme being a pilot means that there are new outputs being developed such as the creation of a new genomic database and a pilot surveillance infrastructure. However, a potential mitigation of these limitations is to understand what was already in place preceding PATH-SAFE and to position the outputs of PATH-SAFE as building on existing capabilities.

Second, our evaluation approach focuses mainly on the PATH-SAFE programme with a limited role for analysing the interactivity with external programmes of work in this space such as the AMR national action plan or the EU Farm to Fork strategy. On a similar note, the lack of international programme assessments means that it is more difficult to position the programme in a broader/international context. Lastly, developments in industry are not factored into the programme itself, so the evaluation has also not included them. This is a blind spot in understanding the state of play in terms of surveillance.

Third, given that much of the anticipated impact of the PATH-SAFE programme will only emerge over a lengthy time horizon, the evaluation will not be able to capture its outcomes nor its long-term impacts in full. Ideally, the evaluation would involve a long-term follow up and assessment of PATH-SAFE to track these impacts of the programme. What we are proposing is a step in this direction, setting out a range of indicators that can be used to assess whether the programme is on track to achieve longer-term desired outcomes and impacts. Additionally,

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the evaluation will provide recommendations on a future-focussed evaluation approach to further the assessment of longer-term outcomes and impacts.

Finally, as the programme is at pilot stage, and our data sources are limited and reliant upon the programme data availability itself, the possibility of low availability of baseline data due to project delays could be a challenge, limiting the range of data available across our evaluation timeline. This lack of data will need mitigation and caveats as the evaluation progresses.

4.   Evaluation framework

This chapter sets out the framework through which the evaluation of PATH-SAFE will be operationalised. The chapter comprises two distinct but interrelated frameworks: a process evaluation framework and an outcome evaluation framework. Presented in tabular form, each framework outlines evaluation questions (EQs), looking to assess progress made towards the PATH-SAFE ToC components. For each EQ, the frameworks contain indicators and proposed data sources that will be used to collect evidence to enable us to answer the EQ. Alongside process and outcome evaluation frameworks, the chapter also provides further detail on the data collection methods and analytical approaches that will be used for each type of evaluation. Impact feasibility is not included in this chapter as Section 3.3 describes the approach that will be undertaken to conduct the feasibility assessment. We have not ascribed indicators and data sources for the ToC impacts at this point as a result.

4.1.   Process evaluation framework

As highlighted in Chapter 3, the process evaluation will seek to understand the extent to which PATH-SAFE's programme governance and resourcing has been fit for purpose and assess the mechanisms of actions across the four WSs. This assessment will be done through the lens of the principles of relevance and coherence based on the OECD criteria. Table 1 below sets out the process evaluation framework. Each WS's activities (A) and outputs (O) are assigned key EQs which will be assessed through the relevant indicators and data sources listed. The last column lists the methodology that will be undertaken for answering each EQ. Sections 4.1.1 and 4.1.2 describe in more detail the data collection tools and analytical approaches that will be used to undertake the process evaluation.

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Table 1. Process evaluation framework

WS	Category	ToC	Key evaluation questions	Indicators	Data sources	Methods
			How appropriately resourced has PATH-SAFE been throughout the stages of inception, design and implementation?	Matching of financial envelope to programme deliverables and targets; number and types of key personnel in place	Management information (project business case and bids and approval outputs); interviews with FSA programme management team	Interviews and documentary review
			How effective and appropriate is the governance in place to support delivery of PATH-SAFE?	Types of governance bodies for example, SAG, DAG, HMT etc. in place and their engagement mechanisms; reporting requirements from PATH-SAFE and its WSs	Interviews with FSA PATH-SAFE programme team and governance documentation	Interviews and documentary review
	Programme-level		How is cross-government interaction being enabled/conducted?	Number and nature of opportunities and communication platforms set up to facilitate cross-govt interaction	Interviews with relevant PATH-SAFE partners and FSA PATH-SAFE programme team	Interviews
				Feedback from inter/cross-govt stakeholders on strength of relationships established and any perceptions of barriers	Interviews with inter/cross-govt PATH-SAFE stakeholders/partners	Interviews
			How is PATH-SAFE linked to existing/developing surveillance programmes?	Level of alignment and linkages between PATH-SAFE and other relevant surveillance programmes mapped and outlined using conceptualisation documents	Management information (project business case and bids and approval outputs); interviews with FSA programme management team; desk research on key surveillance mechanisms across Europe and US (for example, GenomeTrackr) and devolved nations	Interviews, documentary review and desk research

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WS	Category	ToC	Key evaluation questions	Indicators	Data sources	Methods
WS1	Activity and Outputs	**A:** Establish a curated and national FBP (and their AMR) genomic data platform with Salmonella as exemplar pathogen **O:** Functional and scalable data platform that houses sequences and facilitates analysis of exemplar pathogens (for example, Salmonella and their AMR genes **O:** Data platform is interoperable and can interact with other systems like Enterobase and provide an interrogatable user interface	To what extent have relevant end users been engaged and how have their needs been incorporated into the design of the database?	Breadth of end users engaged	Interviews with intended end users and delivery partners; review of updates/notes from delivery board meetings, discovery project outputs and end user reports	Interviews and documentary review
				Satisfaction of end users	Interviews with intended end users	Interviews
			How has data interconnectivity and interoperability been considered in designing the platform?	Types of databases and datasets consulted for interoperability (for example, NCBI, Enterobase, etc.)	Review of highlight reports and DAG and SAG reports	Documentary review
				Interoperability assessments undertaken and recommendations	Interviews with delivery partners	Interviews
				Data access and sharing arrangements in place	Interviews with delivery partners and FSA management; review of DES/highlight/DAG/SAG reports	Interviews and documentary review
WS2 + WS1b	Activity and Outputs	**A:** Pilot new FBP and AMR surveillance approaches based on regular, multi-location sampling in a range of settings, combined with novel technologies (for example, WGS) **O:** AMR and FBP and AMR curated sample data captured from multiple sources, and tested using novel analysis techniques **O**: Evidence on the utility	What existing and novel analysis technologies are being utilised?	Number and type of analysis technologies being utilised; assessment of existing capability utilisation	Interviews with sponsors and delivery partners; review of highlight/activity reports	Interviews and documentary review
			What is the extent of data collection and curation?	Number of samples taken; number of sampling sites accessed; number of genome sequences generated	Delivery partners reports/Delivery board updates	Documentary review
			How (if at all) are new capabilities being generated to improve surveillance	Consolidation of sampling and data curation outputs; number of new tools and models developed;	Interview with sponsors and delivery partners; review of highlight and activity reports	Interview and documentary review

WS	Category	ToC	Key evaluation questions	Indicators	Data sources	Methods
		and suitability of the piloted FBP and AMR surveillance and modelling approaches	How is data being accessed/ shared across relevant stakeholders and departments?	Data access and sharing arrangements in place	Interviews with delivery partners and FSA management; review of highlight/DAG/SAG reports	Interviews and documentary review
WS3	Activity and Outputs	A: Map and test new and repurposed technologies for rapid onsite FBP testing in collaboration with end users O: TRL assessment of rapid onsite FBP testing tools with end users O: Evidence on utilising COVID-19 testing technology (LAMP) for FBP detection in wastewater	To what extent is the TRL assessment approach valuable for identification of relevant technology?	Type of technologies being assessed; review of process of assessment; end users views on TRL assessments and other outputs being fit for purpose	Interviews with delivery partners and end users; review of activity reports and TRL assessment outputs	Interviews and documentary review
			To what extent has the work divulged utility of LAMP as a feasible method? How is LAMP assessment feeding into TRL mechanisms for FBP diagnostics?	Assessment of utilisation of WS3b outputs into 3a	Interview with delivery partners; review of activity reports and TRL assessment outputs	Interviews and documentary review
WS4	Activity and Outputs	A: Develop a pilot AMR surveillance system based on mechanisms of AMR spread in the environment O: AMR surveillance framework and suite of diagnostics enabling monitoring of AMR across the environment within a catchment area	What is being learnt and incorporated from existing AMR surveillance systems and tools?	Breadth of mapping and engagement with existing AMR surveillance systems and tools	Interviews with delivery partners and review of activity reports	Interviews and documentary review
			How is connectivity between the WS4 AMR environment platform and WS1a being considered?	Engagement between WS4 and WS1a; understanding of interoperability between platforms	Interviews with delivery partners; review of shared terms/project outputs/highlight reports	Interviews and documentary review
			How is evidence being aggregated across the multiple departments involved in WS4 delivery	Assessment of WS4 delivery partner engagement mechanisms and frequency	Review of WS4 governance and reporting mechanisms	Documentary review

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4.1.1. Process evaluation data collection methods

As shown in Table 1, the process evaluation will rely on three main methods of data collection: document review, desk research, and key informant interviews. These data collection methods are described in more detail below.

Document review

We will conduct a review of PATH-SAFE management information such as business case bids, initial design documentation, and governance and monitoring requirements/criteria to further develop our understanding of PATH-SAFE programme processes. Documents to be reviewed will also include programme WS specific documentation such as WS project briefs (noting any changes in scope and delivery), latest highlight reports, and latest documentation for a given month/quarter from the Data Advisory Group (DAG), Shared Outcomes Fund, Scientific Advisory Group (SAG) and the Strategic Board. We will also review WS activity/technical reports where appropriate and available. This will be undertaken at both the interim process evaluation and the final process evaluation stages to assess the extent to which the intended outputs have been delivered.

Desk research

We will review the AMR national action plan and the NBN documents to assess alignment with PATH-SAFE in more detail as helpful context of the process evaluation. We will also undertake a high-level grey literature search to map out key pathogen surveillance initiatives across Europe and the devolved nations in the UK to create a robust assessment of surveillance mechanisms and infrastructure already in place in the agriculture/environment sectors.

Key informant interviews

Alongside document review, data on how the programme has been received by key delivery partners, government stakeholders and any other end users, as well as experience of engagement and incorporation of views into WSs, will be collected primarily through key informant interviews. To inform the process evaluation at the interim stage, we will conduct interviews with:

- Up to four central operational staff at FSA
- Up to 10 delivery partners including academics across WSs 1-4
- Up to 15 end users/key government stakeholders across DEFRA, UKHSA, FSS, EA, DHSC and Public Health Wales and NI, etc.

To inform the final process evaluation (and the outcome evaluation) we will conduct interviews with:

- Up to three central operational staff at FSA
- Up to six delivery partners across WSs 1-4
- Up to 10 key government stakeholders/end users

Interviewees will be selected based on the PATH-SAFE stakeholder database, using a purposive sampling approach to ensure representation across WSs, government departments

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and types of end users. This will be done in consultation with the PATH-SAFE central team at FSA. Interview topic guides and analysis coding will be guided by the evaluation questions as specified in Table 1. We will also complement interviews through engagement with PATH-SAFE central and delivery teams at bi-weekly meetings and attendance at monthly Delivery Board meetings.

4.1.2. Process evaluation analysis

Data collected through the methods above will be brought together and triangulated against our process evaluation framework to create an understanding of how processes supported and/or created barriers in delivery of PATH-SAFE. In addition, to create an exemplified picture of effectiveness of PATH-SAFE processes, we propose to develop two case studies based on existing data collection methods highlighted with a potential for deeper dives into the proposed topics via interviews and documentary reviews.

Case studies

Case studies will be selected purposively and will be used to tease out instances in which processes have worked exceptionally well, or to highlight examples where things haven't gone as expected, highlighting opportunities for improvement. This will be determined through consultation with the programme team and considering the data emerging during the interim process evaluation. We propose to develop two process case studies.

Given the central importance of cross-government engagement, we suggest focusing one case study on exemplifying good practice of an instance where cross-government collaboration has worked particularly well (this could be at central programme or at WS level). The case study will not only centre on what worked well but also look to identify enabling factors and levers for change that could be applied across the rest of the programme.

We propose to focus the second case study on data sharing enablement, given its importance across multiple WSs and the programme as a whole. We will again look to exemplify good practice of where data sharing has been enabled or an agreement put in place and go further to identify what catalysed the process and what barriers remain to be addressed.

4.2.   Outcome evaluation framework

As described in Chapter 3 Evaluation approach, the outcome evaluation will provide an assessment of the extent to which the outcomes outlined in the ToC have been realised. This will be a theory-led approach and will utilise CA to validate central claims made about the programme's success, utilising the evidence collected against key outcomes and the key EQs (see section 3.4.1 and 4.2.2 for more info). Within the outcome evaluation framework, most outcomes listed are broadly mapped to the key WSs that are likely to contribute towards them, but some are at a programme-level, to which all WSs are anticipated to contribute. All outcomes have been assigned key EQs which will be assessed through the relevant indicators and data sources listed. The last column lists the methodology that will be undertaken for

answering each EQ. Section 4.2 describes in more detail the data collection tools and analytical approaches that will be used to undertake the outcome evaluation.

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Table 2. Outcome evaluation framework

Workstream	Category	TOC	Key evaluation question (s)	Indicator	Data source	Method
WS1	Outcome	Key stakeholders can more easily share and access data across organisations for rapid identification and tracking of foodborne pathogens and AMR, bringing together multiple data sources	Has data access, sharing, and use for FBP and AMR been enabled and improved across government departments?	Extent to which data aggregation and analysis is enabled	Review of activity reports/highlight reports and interviews with PATH-SAFE delivery partners and end users	Interviews and Documentary review
				Feedback from end users and delivery partners on data sharing practices and improvements	Interviews with end users, PATH-SAFE delivery partners and key government stakeholders	Interviews
WS1	Outcome	Predictive assessment of risk and threat is enabled when assessing a new isolate through access to a comparative repository of pathogen sequences and metadata	To what extent has the platform supported use of relevant metadata and historic isolates for comparative assessments and risk profiles of FBP?	Availability and use of relevant metadata and historic isolates; number of downloads; types of metadata available	Review of highlight/activity reports; interviews with end users	Interviews and Documentary review
WS2 and 4	Outcome	Improved understanding of source attribution and infection threat of FBP and AMR through various environments and international entry points	How has the collective source detection efforts and use of novel technology translated to (if at all) improved surveillance of FBP and AMR?	Speed of FBP/AMR detection in number of days looking at end to end process	Review of project activity reports/highlight reports	Documentary review
				Comprehensiveness of coverage for example, density of testing, number of sampling sites covered, and sequences curated and comparative strain assessment	Review of project activity reports/highlight reports	Documentary review
				Feedback from end users and relevant PATH-SAFE partners/govt stakeholders on improvements made in surveillance	Workshop with PATH-SAFE delivery partners and key government stakeholders	Workshop

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Workstream	Category	TOC	Key evaluation question (s)	Indicator	Data source	Method
	Outcome	Additional knowledge of how to expand existing surveillance mechanisms to support a robust national surveillance infrastructure and improved monitoring	To what extent have the pilot efforts been able to exemplify practice and enhance national surveillance capability?	Feedback from end users and relevant PATH-SAFE partners on national surveillance capability improvements	Workshop with relevant PATH-SAFE stakeholders (include representatives of UK and devolved governments and their agencies (for example, FSA, DEFRA, Welsh Government), health agencies and health boards (for example, Public Health Wales, UKHSA)	Workshop
	Outcome	Informed consideration, based on evidence surfaced, on how proactive, rapid and efficient management can be used to reduce the risk of FBP and AMR introduction into the wider environment and food systems	What kind of strategies and operations have been enhanced, enabled and influenced (if at all) through the surveillance activities?	Types of strategies and operations that have been enabled; other national strategies and action plans enhanced or influenced (for example, NBN, AMR NAP, etc.); knowledge generated	Review of final reports, board reports, publications/grey lit citations; and interviews with FSA programme management	Interviews and documentary review
WS3	Outcome	Guide the use of novel and existing/repurposed rapid onsite FBP testing technology with improved knowledge of where further development is needed	Have the tools identified been useful for end users? Can they be utilised? To what extent have gaps been identified to further development of onsite rapid FBP detection?	Types (and number) of technologies and tools identified; feedback from end users on relevance and utility; evidence of gaps identified to proceed further on tech development	Review of project activity reports/highlight reports; end user interviews	Interviews and documentary review
Programme-level	Outcome	Key stakeholders and decision makers are brought together to	How has PATH-SAFE (if at all) enabled a community of practice and decision	Feedback from end users and policymakers on awareness of	Workshop with relevant PATH-SAFE stakeholders (including representatives	Workshop

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Workstream	Category	TOC	Key evaluation question (s)	Indicator	Data source	Method
		engage with evidence and take forward policy recommendations	makers to come together to inform and act on surveillance of FBPs and AMR?	and engagement with PATH-SAFE	of UK and devolved governments and their agencies (for example, FSA, DEFRA, Welsh Government), health agencies and health boards (for example, Public Health Wales, UKHSA)	
	Outcome	Contributing to the 'One Health' ambitions of reducing threats to public health and the ecosystem	How and to what extent has PATH-SAFE evidence (if at all) contributed to national policies and frameworks for improved public health	Knowledge generated (publications/grey lit citations);	Desk research and use of bibliographic databases	Desk research
				Feedback from end users and policymakers on use of PATH-SAFE evidence into policy and strategies for public health, agriculture and environment interventions	Interviews with key government decision makers	Interviews

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4.2.1. Outcome evaluation data collection methods

As indicated in Table 2, the outcome evaluation will draw on a wide range of sources underpinned by four main methodologies: documentary review, desk research, key informant interviews, and a workshop.

Documentary review

Analysis of key activity reports and papers from meetings of the SAG, DAG, shared outcomes fund, and the strategic board will be analysed to assess the extent to which outcomes have been realised. More focus will be placed on direct WS reports to provide a sense of progress towards intended outcomes at the WS level.

Desk research

Desk research will be conducted on Google Scholar to assess grey literature outputs that can be attributed to PATH-SAFE. We will do this for the first 100 hits through a targeted search. In addition, an assessment of publications of academic papers, strategy and policy documents will be conducted through a search on bibliographic data platforms to assess what publications PATH-SAFE has enabled, if any, which will provide an understanding of PATH-SAFE knowledge generation and wider influence.

Key informant interviews

To further strengthen our understanding of the extent and mechanism of outcome realisation, we will conduct key informant interviews. Please note that these will be the same set of interviews that are proposed for the final process evaluation stage to reduce burden on interview respondents. We foresee speaking to the same set of stakeholders and given the parallel timelines of the final process and the outcome evaluation, these set of interviews will look to assess both process and outcome EQs. As mentioned in section 4.1.1, we will conduct the following interviews for the final process and outcome evaluations:

- Up to three central operational staff at FSA

- Up to six delivery partners across WSs 1-4

- Up to 10 key government stakeholders/end users

As with the process evaluation interviews, topic guides will be developed based on the key EQs in Table 1 and Table 2, and all interviews will follow a semi-structured format.

Workshop

Assessment of step changes or any improvements made on high level outcomes of 'improvements in surveillance capabilities and mechanisms' and 'awareness and engagement across government departments and key decision/policy makers' will be more appropriately gleaned through a large workshop/group exercise (with up to 15 participants) undertaken with the relevant stakeholders. The central programme team will be key in determining the most appropriate mix of stakeholders to engage in this exercise.

4.2.2. Outcome evaluation analysis

The evidence from the methodologies outlined above will be triangulated to develop a holistic understanding of the difference PATH-SAFE has made. This will be crucially underpinned by undertaking a contribution analysis exercise (detailed below) and development of two case studies exemplifying a select component of a given outcome.

Case studies

Case studies will be selected purposively and will be used to tease out instances where tangible examples of progress can be seen towards outcome realisation and/or to highlight examples where things haven't gone as expected, or where outcomes have been significantly delayed, highlighting key barriers. This will be determined through consultation with FSA and considering the data emerging during the early phase of the outcome evaluation. We propose to develop two outcome case studies.

We propose to focus one case study on showcasing an example (if available) of PATH-SAFE influencing a nationally linked operation/strategy (for example, the NBN), and focus on the enablers of influence and the nature of the influence to understand its importance. We propose to focus the second case study on an example of a novel tool or framework for testing/surveillance that has been developed and assess its value to improvement of surveillance.

Contribution analysis

As mentioned before, CA is a method for assessing causal claims that provides a framework for capturing progress towards aims through testing working hypotheses and establishing a case to explain the contribution made by PATH-SAFE and its projects over alternative hypotheses. The six steps involved in CA are as follows:

1. Set out the cause-effect issue to be addressed.

2. Develop the postulated ToC and risks to it, including other influencing factors.

3. Gather the existing evidence on the ToC.

4. Assemble and assess the contribution claim, and challenges to it.

5. Gather new evidence from the implementation of the intervention.

6. Revise and strengthen the contribution story.

At this stage of the evaluation, Steps 1, 2 and 3 have been completed. Based on our understanding of what PATH-SAFE is aiming to achieve and the ToC underpinning the evaluation, we propose three main contribution claims for the programme as an output of Step 4. These are hypotheses that are central to the programme and can be interpreted as high-level and holistic outcomes of the programme.

- The processes established in PATH-SAFE programme **lead to** cross-government collaboration on FBP and AMR surveillance **because** of increased transparency and engagement across departments through the work on interrelated WSs.

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- The development of the data platform in PATH-SAFE **leads to** easier data sharing across government departments **because** of data sharing agreements put in place and extent of user engagement carried out.

- The collective outputs of the WSs in PATH-SAFE **leads to** establishment of a nationally connected and improved FBP and AMR surveillance approach **because** of multilocation sampling, novel testing tools and an interconnected data platform.

We plan to utilise the process and outcome evaluation evidence holistically (for example, evidence from interviews, workshops and case studies) to address Step 4 in assessing the body of evidence to validate the contribution claim. We will then create an overarching narrative (for example, the contribution story) relative to the strength of the evidence that makes a qualitative judgement on whether the contribution claims stand or whether an alternative hypothesis exists for what caused the change to occur. The alternative hypothesis in particular will be tested through interviews and a workshop, and will be derived from the external initiatives listed in Section 2.2.2. The contribution story will identify any gaps in the evidence or weak links, where we will look to alternative sources of data and revise the contribution narrative accordingly. The contribution narrative will ultimately rest on the collective evidence surfaced through the process and outcome evaluations.

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5. Timelines and deliverables

This chapter sets out our timelines for the evaluation and the main deliverables and deadlines.

5.1. Evaluation plan

A Gantt chart visualising the planned timeframe for the implementation of evaluation activities is presented in Figure 5. The deliverables along with their deadlines are highlighted in Table 3. The final report will be prepared by June 28, 2024.

Task	2022		2023													2024					
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	
Developing a programme TOC		■																			
Light touch stakeholder engagement																					
Desk-based research and documentation review																					
D1: TOC for programme		◇																			
M&E framework for programme and workstreams			■	■																	
Refinement and mapping of EQs																					
Indicator development and feasibility assessment																					
Indicator validation: monitoring/assessment of reporting frequency																					
Indicator validation: process and outcome evaluations																					
D2: M&E plan			◇																		
Process evaluation					■	■	■	■	■	■	■	■	■	■	■	■					
D3: Process evaluation plan					◇																
Desk research																					
Document review																					
Interviews																					
D4: Process evaluation - interim report										◇											
Document review																					
Interviews																					
Case study development																					
Evidence synthesis																					
D5: Process evaluation - draft final report																◇					
Outcome evaluation and impact feasibility study													■	■	■	■	■				
Outcome evaluation plan					◇																
Document review and desk research																					
Interviews																					
Workshop/focus groups																					
Case study development																					
Contribution analysis and evidence synthesis																					
Impact feasibility assessment using CMO																					
D6.1: Outcome evaluation - draft final report																◇					
D6.2: Impact feasibility assessment report																		◇			
Reporting and dissemination																		■	■		
Report revisions																					
Dissemination activities																					
D7: Final report and dissemination																				◇	

Legend: ■ Overall task duration · Sub-task duration · ◇ Deliverable
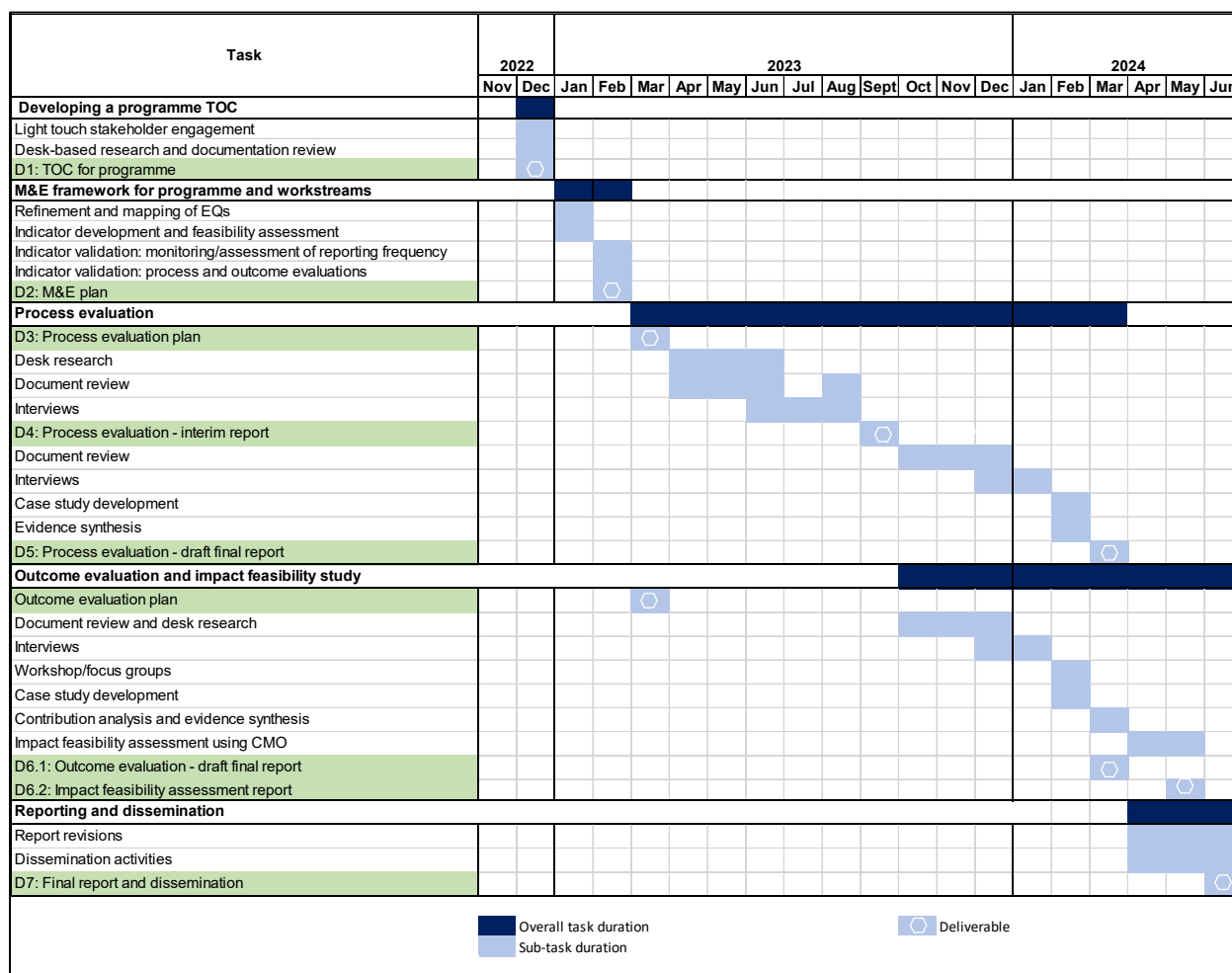
Figure 5. PATH-SAFE evaluation Gantt

5.2. Evaluation deliverables and deadlines

Table 3 below shows the main deliverables and their associated deadlines for the project.

Table 3. Main deliverables and deadlines

Deliverable	Phase	Due date
Theory of Change for programme	D1	December 20, 2022
Monitoring and Evaluation Plan	D2	February 24, 2022
Evaluation framework report	D3	March 31, 2022
Process and output evaluation – interim report	D4	September 4, 2023
Process and output evaluation – draft final report	D5	March 25, 2024
Outcome evaluation draft final report	D6.1	March 25, 2024
Impact feasibility study	D6.2	May 3, 2024
Final report and dissemination	D7	June 28, 2024

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6. Evaluation risks

This chapter considers potential risks to the evaluation of the PATH-SAFE programme and outlines mitigation approaches.

Table 4. Evaluation risks and mitigations

Identified risk	Likelihood of risk (high, medium, low)	Impact of Risk (high, medium, low)	Risk management strategy
Complex policy environment makes it difficult to attribute contributions of PATH-SAFE to outcomes	High	Medium	The programme has been delivered in an evolving and fluid policy environment, which makes attributing impacts directly to PATH-SAFE challenging. Adopting contribution analysis will help clarify what PATH-SAFE has delivered and consider any alternative hypotheses.
Low engagement of stakeholders in interviews	Medium	High	Since there is a risk of a low response rate if PATH-SAFE stakeholders have not been properly introduced to the evaluation and its importance, we will look to draw support from the central programme team in engaging with stakeholders to contribute to the evaluation.
Outcomes have not fully emerged during the timeframe of the evaluation	High	Medium	PATH-SAFE is a large, complex programme whose outcomes may take several years to fully emerge. Given that the programme began in early 2022 and the evaluation will conclude in 2024, many of these outcomes will not be captured. However, by rigorously assessing outputs and outcomes which are apparent, we can determine whether PATH-SAFE is on track to accomplish its intended outcomes and what further actions are required to maximise them.
Lack of counterfactual to assess additionality of the programme	High	Low	As PATH-SAFE is a pilot programme, and is multifaceted and multisectoral, it would be unlikely to find a counterfactual suited for this evaluation to determine additionality of PATH-SAFE. However, given the fragmented surveillance ecosystem and the need for a 'One Health' approach, assessing the value add of PATH-SAFE will be measured against what predated the programme in surveillance capabilities and way of working.
Low quality/availability of data	Medium	High	Where there are considerable gaps or certain documents are unavailable, we will discuss with the central programme team and our experts to identify the best way forward. The overall evaluation will draw on additional insights from interviews, focus, case studies and wider secondary data to ensure multiple data avenues are available.
Risks related to reliance on secondary data	Medium	Medium	We will use mixed methods to mitigate limitations of individual datasets. While we plan to rely heavily on secondary data, this will be complemented by primary data collection through interviews and focus groups, allowing triangulation of sources to ensure an evaluation that is as robust as is feasible.

Identified risk	Likelihood of risk (high, medium, low)	Impact of Risk (high, medium, low)	Risk management strategy
Direction and coverage of the evaluation is not as expected by the programme	Low	Medium	RAND will maintain regular dialogue and engagement with central programme team and use this report as an opportunity for feedback on the approach to ensure alignment.
Poor quality of outputs	Low	High	All RAND reports go through quality assurance (rigorous peer-review by two independent reviewers) ensuring their quality.
Poor communication with the central programme team	Low	Low	Frequent communication with the FSA is included in the project plan through bi-weekly meetings and emails. We will also be attending monthly Delivery Board meetings.
Scope creep and moving goal posts	Low	Medium	The scope and objectives of the study will be confirmed and finalised through the approval of this evaluation framework report; should any changes be necessary over the course of the project, they will be agreed in writing between the study team and FSA; regular communication with the central programme team maintained through regular calls and/or e-mail; project manager acts as the main points of contact for the central programme team if any issues come up.
Overrun of timescales	Low	Medium	Our strong project management and experienced team should ensure that the project runs to schedule and that the FSA is kept regularly informed of developments. RAND Europe's management information systems provide detailed weekly information on the status of each project and each team member, allowing project managers to respond rapidly to any issues arising.
Data and security breaches	Low	High	All data collection and processing will be in line with GDPR requirements as RAND Europe is ISO27001 certified, and we have in-house GDPR support.
Delays to WS outputs and overrun of the programme	Med	High	Overrun of programme/WS outputs will entail adaptation of our questions and indicators to assess progress towards the anticipated objectives.

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Annex A. Overview of PATH-SAFE WSs and Projects

Table 5. Overview of PATH-SAFE WS activity

Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project		Timeline
FSA	WS1 - Establish a curated and national foodborne disease genomic data platform	*Salmonella*	1a	The flagship project of PATH-SAFE. Providing recommendations for building an end-user organisation-independent, interoperable system that will collate raw *Salmonella* WGS data, post-processed and analysed WGS data, and a small subset of related isolate or sample metadata to predict, detect, and proactively mitigate *Salmonella* outbreaks through generating comprehensive low-level and high-level reports.		Discovery 1: completed Discovery 2/CIP: complete Dec 2022 CDP: Jan 2023-Mar 2024 Enterobase: Jan 22-March 24
FSS		*E. coli*	1b	Known as 'the Scottish pilot'. Understanding source attribution, infection threat and level of AMR of *E. coli*. isolated from a range of different reservoirs in Scotland, including animal hosts, wastewater, shellfish, food and humans (for example, determining which *E. coli* (and their resistance genes) are present in food and how these relate to those that can be associated with serious disease in humans).		Underway to March 2024
DEFRA	WS2 - Pilot new FBP	*Salmonella, Listeria, Norovirus, E. coli*	2a.Study A	Providing evidence to	Comparing pathogen prevalence and diversity in two river catchments and	Jan 2023 to March 2024

Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project		Timeline
	and AMR surveillance tools using novel technologies (for example, WGS) based on regular, multi-location sampling in a range of settings			support integrated, effective and cost-efficient targeting of surveillance measures that will aid the prevention and/or mitigation of FBP outbreaks and increase understanding of transmission routes for AMR genes.	assessing onward pathogen transport. Focus on *Salmonella, Listeria*, and *E.coli*.	
			2a.Study B		1. Understanding the temporal and spatial distribution of Norovirus in England and evaluating the effectiveness of wastewater-based epidemiology (WBE) for Norovirus surveillance. Focus on Norovirus.	Jan 2023 to March 2024
					2. Assessing the effectiveness of wastewater surveillance for *Salmonella* and providing genomic sequence data on the diversity of *Salmonella* to feed into the WS1 database. Focus on *Salmonella*.	Jan 2023 to March 2024
			2a.Study C		Known as 'the Bangor study'. Investigating the potential use of data-driven 'active management' approaches to monitor, predict and limit the spread of microbial pathogens and the resistome in the context of recreational waters (for example, rivers, coastal zone) and shellfisheries in Wales. Focus on AMR and Norovirus.	Jan 2023 to March 2024
FSA		*E. coli, salmonella, listeria, campylobacter, enterococci, S. aureus*, ESBL producing *E. coli*, ESBLs, Carbapenemase	2b.1	Focus on determining impacts on agri-food system	Investigating AMR genotypes of ESBL/ampC/carbapenem/colistin isolates being collected through AMR monitoring of raw retail meat in 2021 (beef and pork) and 2022 (turkey and chicken) in GB, and from livestock caeca (poultry and pigs)	Underway to March 2024

Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project	Timeline
				from Northern Ireland (NI) since 2015, to help determine any changes in the AMR trends within UK. Focus on *E. coli.*	
			2b.2	Piloting a novel approach for AMR surveillance in livestock (using sheep) with whole genome sequencing (WGS) and metagenomics approaches alongside phenotypic testing in the abattoir environment and wastewater. Focus on *Salmonella, E. coli, Enterococci*, and *Campylobacter*.	Began in Jan 2023
			2b.3	Establishing the prevalence of AMR in indicator organisms and foodborne pathogens in UK cattle at slaughter and comparing the results to existing surveys of beef at retail. Focus on *E. coli,* ESBLs, Carbapenemase, *Enterococci, Campylobacter*	Began in Jan 2023
			2b.4	Providing an overview of AMR genes and AMR bacteria in raw milk. Focus on *E. coli*, ESBL producing *E. coli, Enterococcus, S. aureus*	Began in Jan 2023
			2b.5	Identifying raw animal feed ingredients and countries of origin presenting the greatest risk of introducing AMR into UK agri-food chains. Focus on *Salmonella*.	Began in Jan 2023

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Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project	Timeline
		Norovirus, influenza, SARS-CoV-2	2c	Known as 'the NI pilot'. Determining if building-level wastewater sampling can be used to detect AMR and screen for Norovirus in 2 care homes in NI.	Began in Jan 2023
		Campylobacter	2d	Investigating routes of transmission and levels of AMR amongst *Campylobacter* isolates from UK Agri-Food sources.	March 2023 - March 2024
		Salmonella	2e	Identify appropriate pathogen isolate collections that could be whole genome sequenced to generate background data on the genomic diversity of foodborne pathogens in the UK, and to feed into the WS 1a data system. Small piece of work.	By March 2023
FSA	WS3 - Map and test new and repurposed technologies for rapid onsite FBP testing in collaboration with end users	Norovirus, *Campylobacter, Salmonella, Listeria, Clostridium*	3a	Landscaping and TRL study. Testing the feasibility of using portable diagnostics as inspection tools for FBP. The results will inform a pilot in-field testing study to create a legacy output which can then be used to prime future studies.	Underway to March 2024

RAND Europe

Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project	Timeline
UKHSA		Norovirus, *Listeria, Salmonella,* Adenovirus, Astrovirus, Rotavirus, Sapovirus	3b	Repurposing rapid, in-field wastewater diagnostic technology that were developed in response to the COVID-19 pandemic for detection of foodborne pathogens and demonstrating its viability, economic and informational value, and versatility in one or more agri-food settings. [Linked to WS3a (results may have an impact on the technology readiness level assigned to loop-mediated isothermal amplification (LAMP) for FBP detection) and the other wastewater work (WS1b, WS2a, WS2b, WS2c, WS4)]	Underway to March 2023
DEFRA & UKHSA	WS4 - Develop a pilot AMR surveillance system based on mechanisms of AMR spread in the environment	Applied methodology: Testing comprehensive range of methodologies to examine AMR in a range of environmental media (river water, bioaerosols and shellfish) Applied methodologies include: Surface (river) waters: - Phenotypic testing of total and ESBL-*E. coli*, total and vancomycin-resistant *Enterococcus*	n/a	Testing a comprehensive range of methodologies to assess the role and impact of AMR in the natural environment (for example, river water, bioaerosols and shellfish). Environment focus (impact on anything outside of agri-food system).	Underway to June 2023

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Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project	Timeline
		sp., yeast and mould species - Antimicrobial Susceptibility testing of bacterial and fungal isolates - Whole Genome Sequencing of bacterial isolates - Metagenomic Sequencing - High-Throughput detecting and quantification of 248-384 Antimicrobial Resistance Genes - Chemical analysis of 41 antimicrobial substances Bioaerosols: trial of sampling methods to determine AMR in airborne microorganisms			

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Responsible government department	Work Stream (WS)	Target pathogens	WS project #	Summary of project	Timeline
		Biosolids: chemical analysis of antifungal residues Shellfish: - Molecular characterisation of AMR in shellfish (targeted metagenomic sequencing of the shellfish microbiome; qPCR of 248 Antimicrobial Resistance Genes) - Enumeration and isolation of resistant E. coli in shellfish flesh - Targeted and Non-targeted chemical analysis of antimicrobial substances			

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Annex B. Evaluation framework report development activities

B.1. Developing a programme theory of change

PATH-SAFE programme partners developed a first draft ToC ahead of RAND being commissioned. As a key underpinning tool for the overall evaluation, we co-designed a refined ToC for the PATH-SAFE programme with the central programme team, outlining the pathways of change for each WS along with their interconnections and dependencies. We utilised the following activities to refine the ToC.

B.2. Documentary review and desk research

To revise the ToC, we conducted a review of key PATH-SAFE documents including relevant business cases and WS documentation outlining aims and ambitions. We also referred to external publications for developing appropriate external factors impacting the ToC and the evaluation such as the [UK 5-year action plan for antimicrobial resistance 2019 to 2024](#), the [UK Government Food Strategy](#), the [Scottish Government Strategy for Environment](#), [Natural Resources and Agriculture Research 2022-2027](#), and [A Green Future: Our 25 Year Plan to Improve the Environment](#).

B.3. Engagement with expert advisors

We consulted with our expert advisors on the project, Dr. Arnoud van Vliet and Dr. Jennifer Ritchie, both from the University of Surrey. Both our advisors have deep expertise in AMR, with Dr. van Vliet providing specialised expertise on foodborne bacterial pathogens and microbial genomics, and Dr. Ritchie on host-pathogen interactions and transmission. Feedback from them helped finetune the ToC and its underpinning assumptions and external factors.

B.4. Central programme team engagement

This included engaging with the central programme team and WS managers through bi-weekly meetings and email exchange. Feedback received from this stakeholder engagement enabled us to further develop the ToC and refine it to reflect the scope and anticipated impact of PATH-SAFE. This initial development was then built upon by conducting a refinement and prioritisation workshop to further refine the ToC. Workshop attendees included stakeholder representatives from the central programme team. Moving forward, it is intended that this report (and thus the ToC and evaluation frameworks) will be shared with other cross-department stakeholders to ensure the validity and utility of the evaluation approach outlined.

Annex C. Process and Outcomes evaluation frameworks development activities

C.1. Document review

This included review of WS specifications, delivery plans and contractual reports available to flesh out the ToC components pertaining to each WS.

C.2. Central programme team engagement

This engagement included meetings with the central programme team, feedback from WS managers, and a refinement and prioritisation workshop. The workshop helped us build on the document review and plug gaps in our knowledge to improve our understanding of the WSs and their interconnectivity and dependencies as well as finetune and prioritise the key EQs. This will be followed up through engagement with other government stakeholders, via FSA, to ensure the validity and utility of the evaluation approach outlined.

C.3. Engagement with expert advisors

We also liaised with our expert advisors, Dr. Arnoud van Vliet and Dr. Jennifer Ritchie, who provided the team with more nuanced information on the important data sources to refer to for key indicators, along with vital feedback on further refining the EQs.